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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,501	09/02/2005	Igor Krisch	LR/G-32980A	4703

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SANDOZ INC
506 CARNEFIE CENTER
PRINCETON, NJ 08540

EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
04/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,501	KRISCH ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-29* is/are pending in the application.

4a) Of the above claim(s) *19 and 26-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-18 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/17/05; 4/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

This Office Action is in response to applicant's remarks filed on 3/26/2008. Claim(s) 15-29 are pending. Claim(s) 19 and 26-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant's election without traverse of the restriction requirement in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL. Claim(s) 15-18 and 20-25 are examined herein insofar as they read on the elected invention and species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-18, 20-22, and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dackis et al. (US Patent No. 4,935,429) in view of Ručman et al. (5,480,885) in further view of Smelson (*Canadian Journal of Psychiatry*, 2002).

Dackis teaches a method of treating psychostimulant addiction more particularly, it relates to a method of inhibiting or eliminating withdrawal symptoms in humans undergoing treatment for central or psychostimulant abuse and to a method of preventing craving after withdrawal by the administration of a dopamine agonist (column 1, lines 14-20). The psychostimulants taught are amphetamine, dextroamphetamine, methamphetamine, and pemoline or a pharmaceutically acceptable acid addition salt thereof (claim 4) and cocaine (claims 15-17).

The dopamine agonist, taught by Dackis, can be any dopamine stimulating agent, in particular, but not limited to, several ergoline derivatives including, bromocriptine, pergolide, lisuride and lergotrile (column 2, lines 46-49).

Furthermore, Dackis teaches the daily dosage for the ergolene and ergoline type dopamine agonist will be from about 0.05 to about 20 mg per day (column 2, lines 62-64).

Dackis does not specifically teach the ergoline derivative 9,10-didehydro-N-methyl-N-(2-propynyl)-6-methyl-8β- aminomethylergoline.

Ručman teaches the 9,10-didehydro-N-methyl-N-(2-propynyl)-6-methyl-8β-aminomethylergoline (column 3, lines 55-65).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the ergoline derivatives to treat psychostimulant addiction as taught by Dackis and have also used the ergoline derivative 9,10-didehydro-N-methyl-N-(2-propynyl)-6-methyl-8β-aminomethylergoline as taught by Ručman. The motivation is that one would expect with a reasonable degree of success that similar results will be obtained by substituting one ergoline derivate for another, in the absence of unexpected results, in particular when both derivatives are agonists at the dopamine receptor.

Claims 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dackis (US Patent No. 4,935,429) in view of Rucman (US 5480885) as applied to claims 15-18, 20-22, and 24-25 above in further view of Glavan (*Molecular Pharmacology*, 2002)

Dackis is discussed above. Dackis teaches, when appropriate, the dopamine agonist employed may be in the free base form or in a pharmaceutically acceptable salt form, namely the mesylate or hydrochloride salt.

Dackis does not teach the bimaleinate salt.

Glavan teaches the bimaleinate salt of 9,10-didehydro-N-methyl-N-(2-propynyl)-6-methyl-8β- aminomethylergoline (page 360, column 2, lines 1-2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the mesylate or hydrochloride salts taught by Dackis and also used the bimaleinate salt as taught by Glavan to make the respective bimaleinate salt of 9,10-didehydro-N-methyl-N-(2-propynyl)-6-methyl-8β- aminomethylergoline. One would be motivated to do so because it is obvious to form salts from known acids. *In re Williams*, 89 USPQ 396 (CCPA 1951).

Conclusion

Claims 15-18 and 20-25 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sahar Javanmard whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617